

## **510(k) Summary**

### **As Required by 21 section 807.92 ( c )**

- 1-Submitter Name:** A & A Medical, Inc.  
**2-Address:** 9370 Industrial Trace  
Alpharetta, GA 30004  
**3-Phone:** (770) 343- 8400  
**4-Fax:** (770) 343- 8985  
**5-Contact Person:** Jihad Mansour  
**6-Date summary prepared:** May 11<sup>th</sup>, 2001  
**7-Device Trade or Proprietary Name:** Laminaria  
**8-Device Common or usual name:** Laminaria digitata  
**9-Device Classification Name:** Hygroscopic laminaria cervical dilator  
**10-Substantial Equivalency** is claimed against the following device:
- Staol Laminaria Tents from Norscan Trading Group

#### **11-Description of the Device:**

This single use device is a hygroscopic laminaria cervical dilator designed to dilate (stretch open) the cervical os by cervical insertion of a cylindrical and expansible material into the cervical canal, made from the root of a seaweed (laminaria digitata). Laminaria expands when it absorbs moisture. The ability to increase in size slowly (usually 6 to 24 hours) is of advantage in physiologically dilating a closed body orifice such as the cervical canal. When used improperly, it may cause the patient major discomfort or uterine complications

Laminaria is available in 2, 3, 4, 5, 6, 7, 8 and 9 mm diameter sizes with a length varying between 50 and 65 mm. Each laminaria is drilled and attached to a 75-95 mm string to facilitate removal from the cervical canal (the last digit of the product code reflects its size)

Laminaria is intended for use whenever it is desirable to dilate the cervical canal, such as uterine or suction curettage, labor induction, IUD placement and removal, and Radium placement

#### **12-Intended use of the device:**

Laminaria is intended for use whenever it is desirable to dilate the cervical canal, such as Uterine curettage, Labor induction, IUD placement and removal, and Radium placement

#### **13-Safety and Effectiveness of the device:**

This device (**Laminaria**) is safe and effective as the other predicate device cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

**14-Summary comparing technological characteristics with other predicate device:**

Please find below a tabulated comparison supporting that **Laminaria** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

|  |  |
|--|--|
| FDA file reference number                        | 510k 951330  |
| Attachments inside notification submission file  | <b>VERY IMPORTANT: REFER TO TABLE ON PAGE 12 OF 13 FOR DETAILS</b> |
| <b>TECHNOLOGICAL CHARACTERISTICS</b>             | <b>Comparison result</b>   |
| Indications for use                              | Identical  |
| Target population                                | Identical  |
| Design   | Identical  |
| Materials  | Identical  |
| Performance                                      | Identical  |
| Sterility  | Similar (Ethylene Oxide but different parameters)                  |
| Biocompatibility                                 | Identical  |
| Mechanical safety                                | Identical  |
| Chemical safety                                  | Identical  |
| Anatomical sites                                 | Identical  |
| Human factors                                    | Identical  |
| Energy used and/or delivered                     | Identical  |
| Compatibility with environment and other devices | Identical  |
| Where used                                       | Identical  |
| Standards met                                    | Identical  |
| Electrical safety                                | Identical (not applicable)   |
| Thermal safety                                   | Identical (not applicable)   |
| Radiation safety                                 | Identical (not applicable)   |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL - 9 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jihad Mansour  
Quality and Regulatory Manager  
A&A Medical, Inc.  
9370 Industrial Trace  
ALPHARETTA GA 30004

Re: K011512  
Hygrosopic Laminaria Cervical Dilator  
2mm, Model RS8-200/2; 3mm, Model RS8-200/3;  
4mm, Model RS8-201/4; 5mm, Model RS8-201/5;  
6mm, Model RS8-202/6; 7mm, Model RS8-202/7;  
8mm, Model RS8-203/8; 9mm, Model RS8-203/9  
Dated: May 11, 2001  
Received: May 16, 2001  
Regulatory Class: II  
21 CFR §884.4260/Procode: 85 HDY

Dear Mr. Mansour:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K011512

Device Name: Laminaria

Indications For Use:

Laminaria is indicated and intended for use whenever it is desirable to dilate the cervical canal, such as Uterine curettage, Labor induction, IUD placement and removal, and Radium placement

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

David G. Seymour  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number

K011512